REMARKS

Claims 1-17 are under examination. Claims 18 and 19 have been withdrawn for covering a non-elected invention. By this amendment, claims 1, 2, 4 and 9-17 are amended. Claims 3 and 5-8 are cancelled. No new matter has been added.

Claim Rejections Under 35 U.S.C. §112-Enablement

Claims 1-17 are rejected as allegedly lacking enablement. The Examiner contends that, while the specification enables PLGA microspheres containing birch pollen extract and having lectin on the cell surface, it does not enable all antigen/allergen containing microspheres having the claimed binding constant or containing antigen mimotopes, without undue experimentation.

This rejection is respectfully traversed. The Examiner appears to be basing a significant part of the rejection on the content of the microspheres. In other words, the Examiner contends that the specification has to enable a representative number of antigens that could be contained in the microspheres *and show an immune response*. However, the claims cover a **product**, *i.e.*, microspheres, and not a method. By this amendment, the term "for allergy therapy" has been deleted from the claim. The invention is microspheres having a certain binding constant based on surface properties, then it is irrelevant what the microspheres contain. The microspheres can theoretically contain *any* therapeutic suitable for the microsphere environment and this should not be subject to an enablement rejection for composition of matter claims.

Withdrawal of this rejection is respectfully requested.

Claim Rejections Under 35 U.S.C. §112-Written Description

Claims 1-17 also stand rejected as allegedly lacking sufficient description in the specification. The Examiner contends that the disclosure of PLGA microspheres containing birch pollen extract and having a lectin on the cell surface does not show that the Applicant "had possession of" *any* microsphere containing *any* antigens/allergens and having the claimed binding constant to any carbohydrate on mucosal epithelia. The Examiner contends that description of a representative number of microspheres having the claimed structural/functional properties is lacking.

Again, the Examiner's reference to the allergen in the microsphere is irrelevant. Further, by this amendment, claim 1 is amended to recite that the microspheres

contain the *Aleuria aurantia* lectin on the surface. Support for this amendment is found in the specification at e.g., paragraph 23-28 on pages 5-6. Because the specification clearly describes microspheres containing the *Aleuria aurantia* lectin that have a binding constant of at least 1×10^4 M^{-1} toward the specific carbohydrate residue of intestinal and/or nasal epithelial cells, this claim is sufficiently described. There is a specifically disclosed correlation between the structure of the microspheres expressing the claimed lectin (*Aleuria aurantia*) and the property of the binding constant.

Withdrawal of this rejection is respectfully requested.

Claim Rejections Under 35 U.S.C. §102-Anticipation

The Examiner contends that claims 1-7 and 9-13 are anticipated by Clark et al., "Lectin-mediated mucosal delivery of drugs and microparticles," *Adv. Drug Delivery Rev.* 2000; 207-223, submitted in an Information Disclosure Statement. The Examiner notes that Clark discloses antigen-containing PLGA microspheres having alpha-L-fucose and the WGA lectin on the surface to increase adhesion to mucosal epithelial cells. Although Clark does not specifically disclose many of the claim limitations, such as the binding constant to the specific carbohydrate residue on nasal/intestinal epithelial cells, and the limitations in claims 10-13, the Examiner contends that, without evidence to the contrary, these would be inherent features of Clark's microspheres.

Applicant notes that the Examiner takes an inconsistent position to that she took for the enablement rejection above, in which she employed the term "for allergy therapy" as a positive limitation for enablement, and now contends that the claim limitation "for allergy therapy" carries no patentable weight for a composition claim. This is incorrect—the "broadest reasonable interpretation" is not capricious based on the specific rejection the Examiner wants to make.

However, to expedite prosecution, the claims have been amended to recite that the microspheres contain the *Aleuria aurantia* lectin on the surface. Such lectin is not disclosed in Clark. Accordingly, withdrawal of this rejection is respectfully requested.

Nor does Clark suggest use of the *Aleuria aurantia* lectin. Clark merely mentions that future studies should be conducted to see whether various lectins may be used to target PLG microparticles to intestinal M cells and whether such targeting would enhance the immune response. Lastly, Clark does not suggest or predict the ability of one lectin over

the other to bind strongly to the carbohydrate residues of intestinal and/or nasal epithelial cells, such as show by the present invention for *Aleuria aurantia*. To the contrary, Clark points to the unpredictable dangers and hurdles that exist with using lectin-conjugated delivery vehicles, particularly for vaccines (see page 219).

EXCEPT for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 13-3250, reference number 37488.00800. This paragraph is intended to be an **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with C.F.R. § 1.136(a)(3).

Respectfully submitted,

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